BEFORE THE DEPARTMENT OF PUBLIC
HEALTH AND HUMAN SERVICES OF THE
STATE OF MONTANA

In the matter of the amendment of ARM 37.86.1101 and 37.86.1105 pertaining to Medicaid reimbursement for dispensing fees and outpatient compound prescriptions	)))))	NOTICE OF AMENDMENT

TO: All Interested Persons

1. On October 25, 2007, the Department of Public Health and Human Services published MAR Notice No. 37-417 pertaining to the public hearing on the proposed amendment of the above-stated rules, at page 1611 of the 2007 Montana Administrative Register, issue number 20.

2. The department is not amending ARM 37.86.1101 at this time.

3. The department has amended the following rule as proposed with the following changes from the original proposal. New matter to be added is underlined. Matter to be deleted is interlined.

37.86.1105 OUTPATIENT DRUGS, REIMBURSEMENT (1) remains as proposed.

(2) The dispensing fee for filling prescriptions shall be determined for each pharmacy provider annually.

(a) The dispensing fee is based on the pharmacy's average cost of filling prescriptions ~~and whether the pharmacy dispenses a generic, preferred drug list (PDL) or non-PDL drug~~. The average cost of filling a prescription will be based on the direct and indirect costs that can be allocated to the cost of the prescription department and that of filling a prescription, as determined from the Montana Dispensing Fee Questionnaire. ~~Considerations in determining the dispensing fee include but are not limited to: prescription volume, overhead costs, pharmacy personnel wages, and special packaging.~~ A provider's failure to submit, upon request, the ~~a properly completed~~ dispensing fee questionnaire properly completed ~~upon request~~ will result in the assignment of the minimum dispensing fee offered. A copy of the Montana Dispensing Fee Questionnaire is available upon request from the department.

(b) The dispensing fees assigned ~~for in-state providers~~ shall range between a minimum of $2.00~~, a $5.50 dispensing fee for non-PDL brand medications and new in-state providers and a maximum of $10.00 for PDL and generic medications~~ and a maximum of $4.70.

(c) and (d) remain as proposed.

(3) In-state pharmacy providers that are new to the Montana Medicaid program will be assigned an interim $3.50 ~~$5.50~~ dispensing fee until a dispensing fee questionnaire, as provided in (2), can be completed for six months of operation.

At that time, a new dispensing fee will be assigned which will be the lower of the dispensing fee calculated in accordance with (2) for the pharmacy or the $4.70 dispensing fee ~~as provided in (2)(b)~~. Failure to comply with the six months dispensing fee questionnaire requirement will result in assignment of a dispensing fee of $2.00.

(4) through (7) remain as proposed.

AUTH: 53-2-201, 53-6-113, MCA
IMP: 53-6-101, 53-6-113, 53-6-141, MCA

4. The department received several comments from providers in support of the proposed dispensing fee amendments to ARM 37.86.1101 and 37.86.1105(2) and (3). The dispensing fee amendments were proposed in response to the pharmacy reimbursement provisions of the Deficit Reduction Act of 2005 (Public Law No. 109-171) and the proposed federal regulations to implement it (42 CFR Chapter IV). Implementation of those provisions have been delayed indefinitely due to a pending lawsuit. Therefore, the department has withdrawn the proposed dispensing fee amendments to ARM 37.86.1101 and restored ARM 37.86.1105(2) and (3) to reflect the withdrawal of those proposed amendments.

5. The department has thoroughly considered all commentary received. The comments received and the department's response to each follow:

COMMENT #1: The compounding drug payment methodology fails to reimburse pharmacists adequately for the time spent, and will limit the access of Medicaid recipients to compounded medications.

RESPONSE: The department disagrees and finds that the proposed compound drug payment methodology is sufficient to determine an adequate reimbursement rate. Montana's proposed rate compares favorably to other state Medicaid compound drug reimbursement methodologies, and other states have not reported access issues. The commentor's statement that this rule would adversely affect recipient access is not supported by the facts. The department has seen a steady increase in the number of compounds billed by line item since it was first allowed in 2004. The drugs compounded using line item billings have included anti-rejection medications, pediatric preparations, and a number of specialty medications.

COMMENT #2: The current system using department assigned local drug codes (00888-codes) is an excellent means by which to bill compounded medications.

RESPONSE: The department disagrees. The department finds it cannot continue to allow the use of local codes for billing compounded medications. These codes neither comply with the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA, P.L.104-191), nor do they allow the department to reimburse only for covered outpatient drugs as mandated by 42 USC 1396r-8.

COMMENT #3: The proposed compounding dispensing fees are unrealistic and will

make it financially impossible for pharmacies to provide compounded medications.

RESPONSE: The department disagrees. The department designed the dispensing fees for compound drugs to compare favorably to those of the Medicaid programs of other states. The proposed amendment maintains Medicaid reimbursement rates while complying with a federal mandate to collect rebates from participating drug manufacturers. The billing requirements will assure continued federal financial participation for compounded prescriptions. Over one-third of the compounds billed to Medicaid in state fiscal year (SFY) 2007 by Montana pharmacies were billed by line item. By substantially increasing the dispensing fees for compounded drugs, the department intends to compensate pharmacies for the additional work generated by the billing requirements.

COMMENT #4: Private third party health plans allow $30.00 plus the average wholesale price (AWP) for ingredients as a compounding fee. Could Medicaid match that dispensing fee?

RESPONSE: Private third party insurers are not restricted by the provisions of 42 USC 1396r-8, so their payment methodologies are not comparable to Medicaid's. Montana Medicaid's dispensing fees for compounded prescription drugs compare favorably with those of other state Medicaid programs.

COMMENT #5: Prior authorization for moderate and high levels of effort for preparing compounds will be time consuming and would cause delay in serving Medicaid recipients.

RESPONSE: The department disagrees. Obtaining prior authorization for mid and high level of effort compounds will take the same amount of time as for other drugs. The Medicaid prior authorization unit is staffed with experienced pharmacists and will be given clear guidelines in determining level of effort parameters. The department's prior authorization unit makes immediate coverage determinations by telephone, and authorizations for new compounds may be expedited by utilizing faxed authorization requests.

COMMENT #6: Montana Medicaid only reimburses for ingredients manufactured by companies that have entered into an agreement with the Centers for Medicare and Medicaid Services (CMS) to pay rebates. It does not pay for excipients or for drugs from manufacturers that do not have a rebate agreement. This policy creates an incentive for compounding pharmacies to maintain a "cash only" business model.

RESPONSE: Medicaid law requires the department to reimburse for drugs within the limits of 42 USC 1396r-8. The department is aware that some compound ingredient manufacturers refuse to sign rebate agreements with CMS, thereby precluding access to their drugs by all Medicaid programs.

The department encourages compounding pharmacies to contact their suppliers and urge them to participate in the Medicaid rebate program. This would ensure access

to quality ingredients for all Medicaid recipients.

COMMENT #7: There are different methods of producing the same compound which result in more or less elegant products. How will the department distinguish such methodologies?

RESPONSE: The department is not able to distinguish different methods of compounding a medication, let alone determine whether one is more "elegant" than another. The department will not attempt to make such distinctions and will rely on the pharmacist's professional discretion and expertise to make effective compounded products.

/s/ John Koch
Rule Reviewer

/s/ Joan Miles
Director, Public Health and Human Services

Certified to the Secretary of State January 7, 2008.